10

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,323	01/18/2002	De-Chu C. Tang	858610-2003.2	3301

20999 7590 09/09/2005

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,323	TANG ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-17,20-26,28-32 and 35-42* is/are pending in the application.

4a) Of the above claim(s) *3,7 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,9-17,20-26,28-32 and 35-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/18/2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

8.00

DETAILED ACTION

This application filed January 18, 2002 is a continuation in part of 09/563,826, filed May 3, 2000, now US Patent 6,348,450, which claims benefit to 60/132,216 filed May 3, 1999; and is a continuation in part of 09/533,149, filed March 23, 2000, now US Patent 6,716,823, which is a continuation in part of 09/402,527, filed January 3, 2000, now US Patent 6,706,693, which is a 371 national stage entry of PCT/US98/16739 filed August 13, 1998, which claims benefit to provisional applications 60/055,520, filed August 13, 1997 and 60/075,113, filed February 11, 1998.

Applicants amendment filed June 15, 2005 has been received and entered. Claims 2, 5, 18, 19, 27, 33, 34 have been canceled. Claim 11 has been amended. Claims 41 and 42 have been added. Claims 1, 3, 4, 6-17, 20-26, 28-32 and 35-42 are pending.

Election/Restriction

Applicant's election with traverse of Group I in the reply filed on August 18, 2003 was acknowledged. The restriction requirement was withdrawn on the ground(s) that it would not constitute an undue burden for examination of both groups.

With respect to the election of species, Applicants elected the species of *Escherichia* with traverse. No new arguments have been made, and the restriction of species is maintained.

The requirement is still deemed proper.

Claims 1, 3, 4, 6-17, 20-26, 28-32 and 35-42 are pending. Claims 3, 7, 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species

of the invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement. Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-42, drawn to a method of non-invasive immunization or induction of systemic immune response to a gene product in an animal comprising contacting the skin of said animal with the species of bacterium *Escherichia* that comprises and expresses the gene product.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

As indicated previously, the listing of references in the specification is not a proper information disclosure statement. Applicants have not commented on this requirement of 37 CFR 1.98(b), in particular that on pages 54-55, the specification provides a list of reference however it is unclear if all are provided in an IDS. Unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Priority

Review of the priority documents indicates that that elected invention a method of non-invasive immunization or induction of systemic immune response to a gene product in an animal comprising contacting the skin of said animal with a bacterium is first present in the instant

application. Since support for the claimed invention is found first in the instant application, it has been given the priority date as of its filing January 18, 2002.

Applicants have not commented on the priority granted the instantly claimed invention.

Specification

The title of the invention is not descriptive. In this case, the bacterial vector of *Escherichia* , not *Salmonella*-based is under examination.

A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

As noted by Applicants, page 6, Section II, the amendment to claim 6 to delete the recitation of the terms "of interest" have obviated the basis of the rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 41 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In this case, the scope of the two claims are exactly the same. It is noted that the wording is a little different in that claim 1 which recites "contacting the skin" and claim 41 recites that "the skin of the animal is contacted", however this slight difference in wording fails to differentiate the scope of the two claims because in both cases the skin is contacted with the vector.

Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40 stand and newly added claims 41 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/346,021. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

claimed methods recite and encompass the same subject matter (see claim 1 with the recitation of 'bacterium'), and dependent claims specifically recite the elected species (see for example claims 2 , 5 and 6).

Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40 stand and newly added claims 41 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/116,963. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods recite and encompass the same subject matter (see claim 1 with the recitation of "bacterial vectors"), and dependent claims specifically recite the elected species (see for example claims 2 and 3).

Applicants not that each of the rejections are provisional, and that it be held in abeyance until allowable subject matter be found. See pages 6-7, Section III.

Applicants' request is noted, however, a rejection can not be held in abayence. Presently, there is no allowable subject matter, and the provisional rejections are maintained for the reasons of record. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40 stand and newly added claims 41 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Krieg *et al.* (US Patent 6,339,068 B1-IDS reference).

Applicants summarize the requirements of 35 USC 102 and contrast the teachings of Kreig *et al.* with the instantly claimed invention noting that Kreig *et al.* teaches only portions of bacterial vectors and fails to teach non-invasisve immunization. More specifically, Applicants argue that the methods of delivering a plasmid using a 'gene gun' taught by Kreig *et al.* can be differentiated from the claimed method in that the present method comprises a non-invasive method of "contacting skin" (claim 1), the skin is contacted (newly added claim 41) or topically applied vectors (newly added claim 42). See Applicants' amendment pages 7-8, Section IV.

Initially, it is noted that Kreig *et al.* teach the use of a plasmid which is propogated and used as a bacterial vector, in particular in *E. Coli.* Examiner would agree that Kreig *et al.* disclose that particular elements of bacterial sequences that affect the immune response in animals, however this would be encompassed by the instant claims as broadly set forth. A review of the present specification for what is contemplated and encompassed by "bacterial vectors" (pages 17-19 of the present specification) does not indicate that any specific type of vector would be excluded. To this end Applicants' arguments are not found persuasive. With respect to the teaching for the use of a gene gun, at issue appears to be what is encompassed by the term "contacting" (claims 1 and newly added 41) and the terms such as "topically applied" (newly added claim 42). A review of the specification fails to specifically set

forth what is encompassed by non-invasive, however can be interpreted in part by what is defined by "invasisve" ("e.g. needle"- page 15, first full paragraph). In determining the breadth of the claims, the claims are given their broadest reasonable interpretation in light of the teachings of the specification. In this case, there is no teaching in the specification that a gene gun would be excluded or that it is not encompassed and/or contemplated. Unlike a needle, the use of a gene gun does not require the use of invasive techniques. Even more generally, at issue is what is considered "non-invasive" since clearly the vectors applied, be it an adenoviral vector or other forms of vectors all invade the surface of the skin and either infect or are taken up by the cells of the subject. In this case, the use of a gene gun is considered a non-invasive means of delivery and is encompassed by the claims as broadly set forth. It is noted that the delivery results in the material being taken-up in the cells on the surface and the epidermis of the skin, however the claims and the specification do not differentiate the claimed invention by this end point, only broadly that as a consequence of delivery a response is induced (claim 1 for example). Applicants' arguments are not found persuasive because the use of a gene gun for immunization as taught by Kreig *et al.* is encompassed by the methods as presently claimed. It is noted that The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration. Attorney argument is not evidence unless it is an admission, in which case, an examiner may use

the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. Also see MPEP 2145.

Again, Krieg *et al.* teach vectors and methods for immunization. The vaccines described by Krieg *et al.* primarily focus on the ability of CpG sequences to enhance the immune response. Krieg *et al.* provide a variety of vectors for practice of the method including the bacteria from which the CpG sequence was first characterized and derived. Krieg *et al.* include the delivery and expression of any gene of interest and includes an extensive list of viral, bacterial and possible cancer antigens as antigens. Additional, it is taught that immunomodulatory sequences can be introduced and expressed to enhance the immune response. Finally, Krieg *et al.* provide a variety of routes of administration known in the art, including the use of a gene gun for the delivery of a vaccine to the skin. The claims encompasses a method of induction of systemic immune response to a gene product in an animal comprising contacting the skin of said animal with a bacterial vector that comprises and expresses the gene product, and the dependent claims set forth specific antigens and animals in which the method is practiced

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Zhang L Biochim Biophys Acta. 2002 Aug 15;1572(1):1-9.Enhanced delivery of naked DNA to the skin by non-invasive in vivo electroporation.

Klavinskis LS Vaccine. 1997 Jun;15(8):818-20Mucosal immunization with DNA-liposome complexes.

Each provide methods for different types of immunization in a model system and different routes of administration.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach